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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/248,178	02/09/99	REED	S 210121.446C2

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SEATTLE WA 98104-7092

EXAMINER

SIU, S

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 04/18/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/248,178

Applicant(s)

REED ET AL.

Examiner

Stephen Siu

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33, 44, 53 and 54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33, 44, 53 and 54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

This is in response to Applicant's response received March 14, 2001 (paper number 16).

The rejection of claims 32 and 43 under 35 USC 112, first paragraph as cited in the prior office action mailed October 31, 2000 (paper number 13) is withdrawn in view of cancellation of the claims.

The following issues are noted:

Priority

It is brought to the applicant's attention that for the purposes of examination priority has not been granted to claimed application 08/998,253, filed December 24, 1997 for the elected invention because it has not been determined that the elected invention was disclosed in the claimed application. Sequence searching of application 08/998,253 did not reveal disclosure of the sequences presently claimed in the instant application. Prior art published after the filing date of application 08/998253 but before the effective filing date of the instant application may therefore be used in the present Office Action. The applicants are requested to provide evidence that the elected invention is disclosed in application 08/998253 if they wish to contest the citation of any intervening prior art.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 33 and 44 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained.

The specification discloses SEQ ID NOs: 55, 56, 59-65 and 67 which corresponds to cDNA encoding a breast protein. The claims are directed to encompass gene sequences, full length genes, and open reading frames. As cited in the prior office action, these sequences do not meet the written description provision of 35 USC 112, first paragraph because the specification provides insufficient written description to support the genus encompassed by the claim. The claims are directed to encompass full length open reading frames, however, no disclosure is provided for full-length open reading frames. The specification discloses only SEQ ID NOs: 55, 56, 59-65 and 67 and therefore, only SEQ ID NOs: 55, 56, 59-65, and 67 meet the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kemp (US Pat No 5536648, 7/16/96, filed 4/18/94) in view of Shattuck-Eidens (US Pat 5709999, 1/20/98, filed 6/7/95).

Kemp discloses an amplified DNA assay wherein detection of target DNA in a biological sample is performed comprising amplifying the DNA by PCR (col.2, lines 1-6). Screening of the target DNA includes screening of human or other mammalian genetic disorders such as in cancer cells (col.6, lines 13-16; col.8, lines 43-45) and detection of target DNA is accomplished in blood, body tissues, etc. (col.6, lines 30-33; col.8, lines 46-48). In the method, PCR is performed utilizing oligonucleotide primers that are complementary to the strands of a target DNA (col.2, lines 55-58) such that the target DNA is amplified. The target DNA is detected in the sample as the sequence that amplifies in the presence of the oligonucleotide primers (col.3, lines 1-6).

Kemp does not disclose the use of the method with particular primer sequences in detection of breast cancer.

Shattuck-Eidens (US Pat No 5709999, 1/20/98, filed 6/7/95) discloses a linked breast cancer susceptibility gene that has 60.5% local similarity to SEQ ID NO: 62 and would thus hybridize to SEQ ID NO: 62.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the method for detecting cancer in a biological specimen derived from a patient using oligonucleotide primers in PCR as per the teachings of Kemp and to further utilize oligonucleotide primers specific for breast cancer such as SEQ ID NO: 62 because a nucleotide sequence of 60.5% local similarity to SEQ ID NO:

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62 that would hybridize to SEQ ID NO: 62 was demonstrated to be associated with breast cancer. Further, Kemp teaches that the method of cancer detection could be used on any body tissue and in cancer cells. Thus, one of ordinary skill in the art would have been motivated to perform the method using the oligonucleotide primers known to be associated with breast cancer through the teachings of Shattuck-Eidens with a reasonable expectation of success of detecting breast cancer.

Claims 53, 54, 33 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kemp (US Pat No 5536648, 7/16/96, filed 4/18/94) in view of Billing-Medel (GenCore 4.5, Accession number V31990, from WO9818945, 07-May-1998).

Kemp discloses an amplified DNA assay wherein detection of target DNA in a biological sample is performed comprising amplifying the DNA by PCR (col.2, lines 1-6). Screening of the target DNA includes screening of human or other mammalian genetic disorders such as in cancer cells (col.6, lines 13-16; col.8, lines 43-45) and detection of target DNA is accomplished in blood, body tissues, etc. (col.6, lines 30-33; col.8, lines 46-48). In the method, PCR is performed utilizing oligonucleotide primers that are complementary to the strands of a target DNA (col.2, lines 55-58) such that the target DNA is amplified. The target DNA is detected in the sample as the sequence that amplifies in the presence of the oligonucleotide primers (col.3, lines 1-6).

Kemp does not disclose the use of the method with particular primer sequences in detection of breast cancer.

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Billing-Medel (GenCore 4.5, Accession number V31990, from WO9818945, 07-May-1998) teaches a nucleic acid sequence associated with breast cancer that has 99.7% local similarity to SEQ ID NO: 56 and contains at least about 15 contiguous nucleotides of SEQ ID NO: 56.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the method for detecting cancer in a biological specimen derived from a patient using oligonucleotide primers in PCR as per the teachings of Kemp and to further utilize oligonucleotide primers that would hybridize to target sequences associated with breast cancer such as SEQ ID NO: 56 because such a nucleotide sequence associated with the breast was disclosed by Billing-Medel. Kemp teaches that the method of cancer detection could be used on any body tissue and in cancer cells. One of ordinary skill in the art would have been motivated to apply the method as taught by Kemp to detecting breast cancer because such a use was suggested through the teachings of Kemp that the method would be used in cancer detection. Sequences specific for cancer of the breast were disclosed by Billing-Medel with homology to SEQ ID NO: 56 such that one of ordinary skill in the art would have been motivated to perform the method using the breast oligonucleotide primers with a reasonable expectation of success of detecting breast cancer.

Conclusion

No claims allowed.

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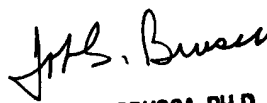
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen C Siu whose telephone number is 703-308-7522. The examiner can normally be reached on M-F, 7:30-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M Woodward can be reached on 703-308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Stephen Siu




JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER